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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,532

Applicant(s)

SCHERSL ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07/17/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 11, 14, 15 and 21-35 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.
3. The rejection of claims 14-35 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.
4. Claims 36-38, 40-46, 48, 50, 52 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they do not end with a period and, thus, the skilled artisan would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 103

5. The rejection of claims 11 and 13-35 under 35 103(a) over Sorkin, Jr. ('393); Gamble et al. ('776); Maurel et al. ('924) and Milstein et al. ('230) in combination is made moot by the cancellation of the instant claims.

6. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. ('393); Gamble et al. ('776); Maurel et al. ('924) and Milstein et al. ('230) in combination.

The instant claims are rejected for the reasons given in the previous Office Action.

Briefly, compositions comprising phytosterols and policosanols are known in the art (see '393, see the entire article, especially col. 1, lines 5-8; col. 3, lines 11-26; examples 1 and 2; col. 2, lines 27-31 and Table I; col. 3, Table II). In addition, phytosterols and policosanols are known in the art to be useful as hypocholesterolaemic agents and, thus, a composition comprising both phytosterols and policosanols for use as hypocholesterolaemic agents would have been prima facie obvious to the skilled artisan in the art (see '776, see the entire article, especially Abstract; col. 4, lines 20-28; col. 5, lines 47-56 and col. 9, lines 44-63; '924, see col. 2, lines 33-46 and '230, see col. 1, lines 18-45).

Again, the recitation of the specific wt % of each phytosterol and policosanol in the claimed composition is noted. However, the court has held that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Russell,

439 F.2d 1228, 169 USPQ 426 (CCPA 1971). Applicant has not provided any factual evidence of record showing the amounts of each policosanol and phytosterol as recited by the instant claims are critical to the instant invention.

Response to Arguments

7. According to applicant, the question to answer is not whether the disclosed composition has or does not have any surprising technical effect, but whether the use of these compositions in food and pharmaceutical formulation for the manufacture of food products or medicament for the reduction of serum cholesterol levels would have been obvious to the skilled artisan. According to applicant, it would and could not have been obvious to the skilled artisan, having regard to the state of art, that the composition of wood alcohols were also effective for the reduction of serum cholesterol levels and, thus, the skilled artisan would not have been motivated to select a mixture of alcohols lacking almost all of the components in the state of art, to be used for reduction of serum cholesterol. Applicant's argument was considered but not persuasive for the following reasons.

If, according to applicant, the issue is whether it would have been obvious to the skilled artisan to use the compositions in food and pharmaceutical formulation for the reduction of serum cholesterol levels, applicant is directed to the teachings of Gamble, Maurel and Milstein. Each of the cited reference teaches the utilization of policosanols or phytosterols in food and pharmaceutical products. In addition, the court has held that the combination of two or more compositions having similar use to form another

composition for the same use is prima facie obvious. Thus, the incorporation of a combination of policosanols and phytosterols into food and/or pharmaceutical products would have been obvious to the skilled artisan.

Applicant also argues that it would and could not have been obvious to the skilled artisan, having regard to the state of art, that the composition of wood alcohols are also effective for the reduction of serum cholesterol levels. First, it is noted that not all of the claims recite compositions comprising wood alcohols. Secondly, the issue is not the origin of the alcohols but the alcohols themselves. The prior art makes obvious the use of long-chained aliphatic alcohols in the treatment of elevated serum cholesterol levels and exemplifies C20 to C39 alcohols whereas the claimed invention recites a composition comprising C18 to C26 alcohols wherein C18 is as little as **approximately** 0.01 weight percentage of C18. Based on the teachings of the prior art, the skilled artisan would have the reasonable expectation that any long-chained aliphatic alcohol, including octadecanol, would be useful in treating elevated serum cholesterol levels. If applicant's argument is that the percent combination of each of the recited alcohol makes the claimed composition novel, it is suggested that applicant provides factual evidence of record showing some unexpected and/or unobvious result based thereon. As stated in the previous Office Action, the recitation of the specific wt% of phytosterol and/or policosanol is not patentable absent a showing of criticality since the selection of proportions and ranges of each in order to obtain a composition having optimum properties would require only routine experimentation which is within the level of skill of the ordinary artisan in the art.

For these reasons and those given in the previous Office Action, the instant claims are rejected as indicated above in #6.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

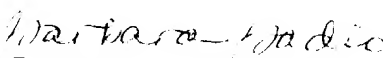
Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badlo, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 2, 2004